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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,940	06/15/2006	Toru Moriguchi	292106US0PCT	9811

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
MI, QIUWEN	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
06/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/582,940	MORIGUCHI ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-36* is/are pending in the application.

4a) Of the above claim(s) *34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 4/15/08 is acknowledged, with the cancellation of Claims 1-15; and the additional newly added Claims 16-36. Claims 16-36 are pending. Any rejection that is not reiterated is hereby withdrawn.

Election/Restriction

Claims 34-36 are withdrawn as they are directed toward a non-elected invention groups. Newly submitted Claims 34-36 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 34 is drawn to invention Group III; Claims 35 and 36 are drawn to invention Group II.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 34-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claim 34-36 drawn to an invention nonelected with traverse in the reply filed on 4/15/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 16-33 are examined on the merits.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 17, 18, 32, and 33 are rejected under 35 USC § 102 (b) as being anticipated by Noble et al (US 5,484,611).

Noble et al teach docosahexaenoic acid linked with phospholipid (claim 1), wherein the docosahexaenoic acid linked with the phospholipid is made into the form of tablets (thus contains a pharmaceutically acceptable carrier), capsules, powder or solution (claim 6). Noble et al also teach a method of a method of treatment of an animal body, comprising administering to the body a composition in biocompatible form which contains docosahexaenoic acid-linked phospholipids wherein said phospholipids are phosphatidyl ethanolamine, phosphatidyl serine and phosphatidyl inositol (claim 9). Noble et al teach that the DHA-phospholipid is effective for treating degenerative disease of brain and nervous system (col 4, lines 23-30). Noble et al further teach that a fatty acid composition and the proportion by weight of the major fatty acids in total phospholipid was palmitic 35.9, palmitoleic acid<1. stearic acid 16.2, oleic acid 16.4, linoleic acid 2.2, linolenic acid<1, arachidonic acid 9.6, and docosahexaenoic acid 17.7 (col 3, lines 25-30).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that it is deemed that the prior art product must

not be precluded for use to improve central nervous function, visual acuity or circulatory function. It is deemed that the composition disclosed by Noble et al. is not precluded for carrying out the intended function of the claims.

Therefore, the reference is deemed to anticipate the instant claim above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noble et al (US 5,484,611), in view of McCleary (US 2002/0182196), and further in view of Bydlon et al (US 2003/0050341).

Noble et al teach docosahexaenoic acid linked with phospholipid (claim 1), wherein the docosahexaenoic acid linked with the phospholipid is made into the form of tablets (thus contains a pharmaceutically acceptable carrier) (a solid), capsules , powder or solution (a liquid) (claim 6). Noble et al also teach a method of a method of treatment of an animal body, comprising administering to the body a composition in biocompatible form which contains docosahexaenoic acid-linked phospholipids wherein said phospholipids are phosphatidyl ethanolamine, phosphatidyl serine and phosphatidyl inositol (claim 9). Noble et al teach that the

DHA-phospholipid is effective for treating degenerative disease of brain and nervous system (col 4, lines 23-30). Noble et al further teach that a fatty acid composition and the proportion by weight of the major fatty acids in total phospholipid was palmitic 35.9, palmitoleic aicd<1. stearic acid 16.2, oleic acid 16.4, linoleic acid 2.2, linolenic acid<1, arachidonic acid 9.6, and docosahexaenoic acid 17.7 (col 3, lines 25-30).

Noble et al do not teach the incorporation of *Gingko biloba*, fish oil, and linseed into the composition, or the ratio of linolenic acid to the phospholipid, or a food or a beverage.

McCleary teaches a nutritional supplement composition for normalizing impaired or deteriorating neurological function comprising phosphatidyl serine, docosahexanoic acid (DHA), and *Gingko biloba* (see Title, Abstract, [0177]). McCleary also teaches that the composition in the forms of capsules, tablets, etc for oral administration [0182].

Bydlon et al teach compositions containing the fatty acid docosahexaenoic in combination with vitamin and mineral as supplement nutrition for health issues particularly associated with cardiovascular and central nervous systems [0021]. Bydlon et al teach that DHA has been found to be important for immunological system, cardiovascular system, and central nervous system [0008], and DHA may be obtained from natural sources include oils and fats from cold-water fish etc, and exemplary sources of DHA includes seed oil such as flaxseed oil etc [0024], and the supplement nutrition overcomes the drawbacks associated with dietary supplements of the prior art [0018].

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use *Gingko biloba* from McCleary since McCleary teaches that the composition normalizing impaired or deteriorating neurological function. Therefore, one of the ordinary skills in the art would add *Gingko biloba* to enhance the effect for treating degenerative disease of brain and nervous system.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the fish oil and flaxseed oil as DHA sources in Bydlon et al since Bydlon et al teach that the supplement nutrition containing DHA are particular useful for health issues associated with central nervous system, and the supplement nutrition overcomes the drawbacks associated with dietary supplements of the prior art.

Since all of the compositions yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate ratio of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as a food or beverage. It is deemed that the composition disclosed by the cited references is not precluded for carrying out the intended function of the claims.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "the fatty acid constituents described in Noble are represented by the R1 and R2 moieties of a phospholipid represented by the general formula…as a result, Noble fails to anticipate or render obvious the presently claimed invention (page 10, 2nd and 3rd paragraphs).

It is not clear how Applicant comes up with the general formula, it is certainly not within the disclosure of Nobel. Nobel anticipates the claimed invention for the reasons stated above. Since the independent claim 16 is rejected under 102, it is not relevant whether the invention exhibited superior properties as compared to the conventional composition (page 9, 2nd paragraph from the bottom).

Applicant's arguments with respect to McCleary and Bydlon have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655